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James E. Bailey New Technology Liaison Pharmaceutical and Technology Ombudsman Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244 Via email to <u>DMEPOS@cms.hhs.gov</u>

Subject: Request for Benefit Category Determination

Dear Mr. Bailey:

On behalf of the American Heart Association (AHA) and the American Medical Association (AMA), we **request a Medicare benefit category determination for self-measured blood pressure (SMBP) devices**. Use of SMBP devices is an evidence-based intervention to help patients with hypertension achieve and maintain blood pressure (BP) control. SMBP devices are used by patients in their homes to monitor their BP. Understanding where their BP is in relation to their target BP level enables patients to adjust their behavior to lower their BP. The information also helps patients understand when they need to communicate with their physician about adjusting medications. This letter focuses on two key points:

- SMBP devices meet the Centers for Medicare & Medicaid Services (CMS) conditions for the durable medical equipment (DME) benefit category.
- SMBP devices are comparable to glucose monitoring devices, as both types of devices provide useful information for patients and their physicians to take action based on the readings.

Hypertension is the number one chronic condition of Medicare beneficiaries

CMS has called hypertension the most important modifiable risk factor for coronary heart disease, stroke, congestive heart failure, and end-stage renal disease. The Centers for Disease Control and Prevention (CDC) identifies heart disease as the leading cause of death in the United States.¹ The CDC also reports that unmanaged hypertension results in nearly 1,300 deaths every day.^{2,3}

Hypertension is the number one chronic condition of Medicare beneficiaries. The Medicare population experiences high rates of hypertension compared with the non-Medicare population; 57 percent of Medicare beneficiaries have hypertension compared to 47 percent of people who are not eligible for Medicare. The prevalence rate of hypertension among Black/African American Medicare beneficiaries is 65 percent.⁴

Monitoring BP at home using a SMBP device is a key component in managing hypertension. When SMBP devices are used to manage hypertension there is evidence to support improved medication adherence, reduction in BP and improved BP control.⁵ Together, these may lead to a reduction in the medical conditions associated with uncontrolled hypertension: heart disease, stroke, chronic kidney disease, cognitive impairment, and premature death.

BP control rates heading in the wrong direction; disparities in outcomes persist

During the first decade of the 21st century, BP control rates steadily improved, but now they are worsening, with an estimated 60 percent of those with hypertension not in control. An analysis of National Health and Nutrition Examination Survey (NHANES) data found that adults with controlled BP increased from 31.8 percent in 1999-2000 to 48.5 percent in 2007-2008. This rate remained stable and then declined to 43.7 percent from 2017-2018.⁶ In addition, ethnic and racial inequities in BP control continue among US adults; for example, a lower proportion of non-Hispanic Black adults have controlled BP compared with non-Hispanic White adults.

What are SMBP measurement devices?

SMBP devices calculate systolic (top) and diastolic (bottom) BP values and provide patients with a digital display of their BP readings. The devices include an adjustable cuff that wraps around the patient's upper arm. A variety of cuff sizes are available to ensure accuracy.

There are two main types of SMBP devices: manual and automatic. Manual SMBP devices consist of a cuff, an inflation bulb and a gauge that is read by looking at a pointer on the dial. Manual BP monitors require the use of a stethoscope to listen to the blood pulsing through the artery. Due to the training and skill required to accurately measure BP with manual SMBP devices, they are not recommended for home use. Automatic BP monitors have upper arm cuffs that automatically inflate, deflate, and calculate a patient's BP. The SMBP device's screen displays a digital readout of the patient's BP. The devices are available for purchase directly from device manufacturers through retail stores such as CVS, Walgreens, Walmart, and Costco, as well as online marketplaces like Amazon.

SMBP devices may be equipped with one or more types of connectivity functions to transfer or store BP readings. These functions include WIFI, Bluetooth, or cellular connectivity. The devices can also vary in terms of the number of BP readings that can be stored on the device, as well as software compatibility with patient or clinic-level management software to compile and analyze BP readings and trends.



Photo of an automatic home BP monitor with arm cuff

How do patients use an automatic SMBP device?

There are many instructional videos, pamphlets, and infographics to assist patients in the proper use of a SMBP device. Members of clinical teams can also educate patients on how to use an automatic SMBP device. The AHA and AMA created <u>Target BPTM</u> to provide physicians and other health care professionals with tools and resources, including patient education materials, to ensure that patients have the information needed to accurately monitor their BP and understand the readings. An example of an infographic is shown below.



How do patients use these devices to control their BP?

The use of a SMBP device is part of an evidence-based approach that can achieve improvements in BP control by facilitating collaboration between patients and clinical teams. The diagnosis and treatment of hypertension begins with an accurate assessment of BP, usually interpreted by the patient's primary care physician. Once a diagnosis of hypertension is made, patients are educated on how to use a SMBP device and, of equal importance, on what to do if the BP readings are too high, too low, or accompanied by symptoms.

Patients are instructed to monitor their BP regularly: ideally twice daily (morning and evening) with two measurements taken each time at least a minute apart. When patients are measuring their BP to share with their physician, they should share a minimum of 12 readings (i.e., three days) taken during a seven-day period. Once BP control is achieved and BP remains stable for several months, monitoring one to three

days (twice daily, morning and evening) every week is probably sufficient.⁷ Patients can transmit the data via the connectivity functions or record them on a <u>paper form</u>.

There are many actions that patients can take utilizing their SMBP readings to better control their BP. These include:

- Making lifestyle modifications (non-pharmacological treatment) that are proven to have a direct impact on lowering BP: eating a heart-healthy diet high in potassium-containing vegetables; lowering salt intake; limiting saturated fat; limiting alcohol consumption; and increasing physical activity.
- Contacting their physician to determine if medication adjustments (pharmacologic treatment) are needed.

When a patient tracks BP readings as recommended in clinical guidelines, they will be better informed of the impacts that their diet and lifestyle have on their BP. For example, if a patient notes that their BP spikes after a salty meal, a cigarette or a drink of alcohol, the importance of adhering to lifestyle modifications to treat their hypertension becomes clear. Additionally, when a patient notes their BP is not at goal, they can immediately make recommended lifestyle modifications to lower their BP through improved non-pharmacologic treatment of their hypertension. Having access to SMBP measurements helps patients make better decisions for treating their hypertension and enables them to communicate important information to their physician and clinical team for pharmacologic treatment changes as indicated. All these treatment options have been shown to lower BP and are linked to reduced risk of heart attack or stroke.⁸



Patients receive education on interpreting their BP readings

SMBP devices hence provide actionable data to patients with hypertension in the same way that glucometers provide actionable data to patients with diabetes. Home glucose monitors are categorized by Medicare as DME.

SMBP devices meet all conditions for the DME Medicare benefit category as defined in regulations:

- Can withstand repeated use Commercial health plan coverage of SMBP devices range from 3-5 years before a replacement is warranted
- 2. Primarily and customarily used to serve a medical purpose The primary purpose of a home BP device is to provide the patient with ongoing monitoring of their BP to determine if behavioral or clinical changes are necessary
- 3. Useful to a person with a diagnosed medical condition Patients with hypertension receive actionable data about their condition that is shared and monitored by a physician-led care team
- 4. Generally, is not useful to an individual in the absence of an illness or injury
- Appropriate for use in the home These devices are specifically designed by manufacturers for home use. More information is available at <u>www.ValidateBP.org</u>

SMBP devices are comparable to glucose monitors for providing patients with actionable data

SMBP devices:

Glucose meters:

Main purposes of self-monitoring	Main purposes of self-monitoring				
Provides patient with regular confirmation of BP status	Provides patient with regular confirmation of glucose status				
Allows patient to adjust non-pharmacological interevention (DASH diet, low sodium intake, increase physical activity) and share BP data with physicians	Allows patient to self-treat including by relaying information to physician				
Includes education on the effects of diet, exercise, smoking, medication adherence on BP levels	Includes education on effects of diet, physical activity and other factors on glucose levels				
Motivates patient to sustain healthy behaviors	Motivates patient to improve health behaviors				
Both SMBP devices and glucose meters are an important part of a team-based approach (which include pharmacists, nurses, community health workers) for chronic disease management can be supported by telemedicine or digital interventions.					

Clinical guidelines recommend non-pharmacological interventions as the cornerstone of treatment for everyone with hypertension or elevated BP to achieve BP control

Lifestyle modifications that improve diet, increase weight loss if overweight, improve physical activity and decrease alcohol use are proven to contribute to lowering BP for adults, including those with hypertension. There is an arsenal of highly effective medications available for managing hypertension, but clinical guidelines recognize the impact of a more comprehensive approach to treating and controlling hypertension that includes lifestyle modifications. The guidance to educate patients on lifestyle behavior change recognizes that drug treatment strategies alone have limitations in reducing morbidity and mortality related to elevated BP.⁹

			Approximate Impact on SBP		
	Nonpharmacological Intervention	Dose	Hypertension	Normotension	Reference
Weight loss	Weight/body fat	Best goal is ideal body weight, but aim for at least a 1-kg reduction in body weight for most adults who are overweight. Expect about 1 mm Hg for every 1-kg reduction in body weight.	–5 mm Hg	-2/3 mm Hg	(56.2-1)
Healthy diet	DASH dietary pattern	Consume a diet rich in fruits, vegetables, whole grains, and low-fat dairy products, with reduced content of saturated and total fat.	–11 mm Hg	-3 mm Hg	(56.2-6,56.2-7)
Reduced intake of dietary sodium	Dietary sodium	Optimal goal is <1500 mg/d, but aim for at least a 1000-mg/d reduction in most adults.	-5/6 mm Hg	-2/3 mm Hg	(\$6.2-9,\$6.2-10)
Enhanced intake of dietary potassium	Dietary potassium	Aim for 3500-5000 mg/d, preferably by consumption of a diet rich in potassium.	-4/5 mm Hg	-2 mm Hg	(56.2-13)
Physical activity	Aerobic	 90-150 min/wk 65%-75% heart rate reserve 	-5/8 mm Hg	-2/4 mm Hg	(56.2-18,56.2-22)
	Dynamic resistance	 90-150 min/wk 50%-80% 1 rep maximum 6 exercises, 3 sets/exercise, 10 repetitions/set 	-4 mm Hg	-2 mm Hg	(56.2-18)
	Isometric resistance	 4 × 2 min (hand grip), 1 min rest between exercises, 30%-40% maximum voluntary contraction, 3 sessions/wk 8-10 wk 	–5 mm Hg	-4 mm Hg	(56.2-19,56.2-31)
Moderation in alcohol intake	Alcohol consumption	In individuals who drink alcohol, reduce alcohol† to: ■ Men: ≤2 drinks daily ■ Women: ≤1 drink daily	-4 mm Hg	-3 mm Hg	(56.2-22-56.2-24)

Resources: Your Guide to Lowering Your Blood Pressure With DASH—How Do I Make the DASH? Available at: https://www.nhlbi.nih.gov/health/resources/heart/hbp-dash-how-to. Accessed September 15, 2017. (S6.2-72) Top 10 Dash Diet Tips. Available at: http://dashdiet.org/dash_diet_tips.asp. Accessed September 15, 2017. (S6.2-73) *Type, dose, and expected impact on BP in adults with a normal BP and with hypertension. fln the United States, one "standard" drink contains roughly 14 g of pure alcohol, which is typically found in 12 oz of regular beer (usually about 5% alcohol), 5 oz of wine (usually about 12% alcohol), and 1.5 oz of distilled spirits (usually about 40% alcohol) (S6.2-29). DASH indicates Dietary Approaches to Stop Hypertension; and SBP, systolic blood pressure.

Organized medicine and federal government support for comprehensive SMBP monitoring

The American College of Cardiology and AHA clinical practice guidelines for the prevention, detection, evaluation, and treatment of high BP in adults state that although 24-hour ambulatory BP monitoring may improve the accuracy of diagnosing hypertension, SMBP monitoring is a more practical long-term approach in everyday clinical practice for diagnosing and assessing BP control over time to manage hypertension.¹⁰ National medical specialty and other professional societies including the American Academy of Family Physicians, American College of Physicians, American College of Preventive Medicine, American Geriatrics Society, American Society of Hypertension, American Society for Preventive Cardiology, Association of Black Cardiologists, National Medical Association, as well as the American Pharmacists Association, all support the use of SMBP monitoring for the diagnosis and management of hypertension.

The CDC 6|18 Initiative, Community Guide, and Million Hearts® initiative recognize the valuable contribution that SMBP monitoring can play in hypertension management. The 6|18 initiative has included expanding access to SMBP monitoring as one of its core strategies, noting that these interventions are both effective and cost-effective compared to usual care.¹¹ The Community Guide found "strong evidence" that SMBP monitoring interventions, when combined with additional support (i.e., patient counseling, education, or web-based support), are effective and cost effective in improving BP outcomes in patients with high BP.¹² Million Hearts® initiative encourages the use of SMBP monitoring as a means to "improve access to care and quality of care for individuals with hypertension while making BP control more convenient and accessible across the population."¹³ In addition, the US Surgeon General's Call to Action to Control Hypertension includes the use of SMBP devices and lifestyle change as evidence-based interventions associated with improvements in BP control.¹⁴

The best available science supports the use of SMBP monitoring for improved management of hypertension

For many people, BP measured in the home differs greatly from BP measured inside a physician's office. SMBP monitoring is a validated approach of measuring BP outside of the clinical setting. SMBP is a more accurate predictor of cardiovascular events and mortality than office-measured BP. Current US clinical guidelines and scientific statements recommend the use of out-of-office BP measurements for confirming and managing hypertension, following up to assess BP control and educating the patient on how to self-measure BP with a home device and interpret and act on the results.¹⁵

By making SMBP monitoring more accessible, regular SMBP measurements over time can reduce BP among older adults¹⁶ and motivate changes in risky behaviors including cigarette smoking and alcohol consumption.¹⁷ By identifying potential risks before they become severe, SMBP monitoring supports older adults in leading independent lifestyles without relying on caretakers or frequent clinical visits.¹⁸

A common recommendation is that self-measured BP monitoring be based on two measurements taken at least one minute apart in the morning and evening (i.e., four readings per day) optimally for seven days (i.e., 28 readings total), with a minimum of three days (i.e., 12 readings total). Once BP control is achieved and BP remains stable for several months, monitoring one to three days a week is probably sufficient.⁷

Historically marginalized populations are disproportionately impacted by hypertension

According to the CDC, an estimated 56.2 percent of Black adults in the US have hypertension compared to 48 percent of White adults.¹⁹ Black adults have significantly higher death rates from stroke than White adults (59 per 100,000 compared to 35.7 per 100,000). An evaluation of disparities in hypertension prevalence, awareness, treatment, and control found that even though awareness of a hypertension diagnosis was similar among White, Black, and Hispanic adults, control rates differed significantly. The control rate for White adults was 49.1 percent compared to 39.2 percent for Black adults and 40 percent for Hispanic adults.²⁰ A recent study by Dr. Reza Mohebi and colleagues projected that while cardiovascular risk factors, including hypertension, will gradually decrease from 2025-2060 for Whites, they will rise exponentially for Black and Hispanic populations. The Black population is projected to experience the highest burden of the increase in cardiovascular risk factors.²¹ While there are considerable challenges to understand and overcome ethnic and racial disparities in the prevalence and treatment of hypertension, it is likely that social determinants of health such as educational status, access to health care, and low income play a key role in prevalence and BP control rates.²²

All patients with hypertension would benefit from a SMBP device

SMBP is recommended for monitoring and improving health outcomes associated with uncontrolled hypertension. The automatic SMBP devices that are currently on the market make it much easier for patients to test and monitor their BP in a non-stressful environment. While all patients with hypertension would benefit from a home BP device, it is especially beneficial to achieve improved control rates for patients with a history of fluctuating BP. Learning how to use a home device and understand how to interpret and act on the readings empowers patients to be an active participant in improving their health outcomes through behavior change. Armed with this information, patients are also able to share the readings with their physician to address any medication adjustments.

Several meta-analyses of randomized controlled trials indicate that the use of SMBP monitoring leads to reductions in BP and improved BP control among individuals with hypertension. Overall, there is strong and compelling evidence to indicate that SMBP monitoring provides benefit to managing hypertension. For adults over age 60, treating hypertension to achieve BP control is associated with reduced stroke and adverse cardiac events.

Home BP devices can empower Medicare beneficiaries with hypertension

Hypertension is the number one chronic condition of Medicare beneficiaries. Based on national data for all adults with hypertension, it is estimated that a third of those have uncontrolled disease. Providing and educating Medicare beneficiaries with home BP devices is a clinically supported, evidence-based intervention to help patients achieve and maintain BP control. Medicare beneficiaries can act on those home readings through changes in lifestyle, and if warranted, adjustments to medications.

SMBP devices meet the conditions that CMS has defined in regulations for DME. Patients can obtain these devices in multiple retail environments and take actionable steps based on the readings just as Medicare beneficiaries do based on the readings from glucose monitors. Therefore, we request a benefit category determination for SMBP devices. Thank you for considering this request. Should you have any questions or need additional information, please contact Margaret Garikes, AMA Vice President, Federal Affairs, at <u>margaret.garikes@ama-assn.org</u>.

Sincerely,

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James L. Madara, MD Executive Vice President, CEO American Medical Association

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Nancy Brown Chief Executive Officer American Heart Association

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